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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,424	01/25/2005	Stephanie Krammer	K21336USWO (C038435/01841	7563

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EXAMINER
ROBERTS, LEZAH

ART UNIT	PAPER NUMBER
1614	

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DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/522,424	KRAMMER, STEPHANIE	
	Examiner	Art Unit	
	Lezah W. Roberts	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *25 Jan 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims

Claim Rejections - 35 USC § 112 – Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6 and 8-16 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating plaque, gingivitis, periodontal disease and oral malodor, does not reasonably provide enablement for "preventing" plaque, gingivitis, periodontal disease and oral malodor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the nature of the invention,
2) the breadth of the claims
3) the relative skill of those in the art,
4) the state of the prior art,
5) the predictability of the art,
6) the amount of direction or guidance provided,
7) the presence or absence of working examples, and

8) the quantity of experimentation necessary,

1) *The nature of the invention.* The invention discloses using a composition comprising a lactoferrin, epigallocatechin gallate, vitamin E, vitamin C and carotenoids to treat plaque, gingivitis, periodontal disease and oral malodor.

2) *The breadth of the claims.* The claims are broad because they read on "preventing".

3) *The relative skill of those in the art.* The relative skill of those in the art are PhD, MD, and MS.

4) *The State of the Prior Art.* The prior art discloses that the disclosed components are used to treat symptoms of periodontal disease.

5) *The Predictability or Lack Thereof in the Art.* Prevention is not practical with plaque, gingivitis, periodontal disease and oral malodor due to the unpredictability of the condition. According to the American Dental Association (http://www.ada.org/public/topics/bad_breath.asp), oral diseases can be caused by health problems (such as diabetes) or lack of getting the oral cavity professionally cleaned. Periodontal disease begins with plaque that is not removed during daily cleaning. When plaque is not removed it turns into calculus. It is impossible to remove all calculus with daily brushing (http://www.perio.org/consumer/faq_general.htm, pages 1-4). The calculus, if untreated, causes gingivitis, the first stage of periodontal disease. Therefore a small amount of gingivitis is always present in between dental visits. In the case of conditions such as halitosis, it may be caused by dry mouth, tobacco products or medical disorders such as liver or kidney ailments. In the case of the instant

invention, periodontal disease can be caused by different factors, therefore it is, practically speaking, impossible to protect against them all with one compound or mouthwash solution.

6) *The Amount of Direction or Guidance Present.* The specification discloses compositions for treating but not preventing the disclosed oral diseases. This guidance or lack thereof is not commensurate with the full scope of the claims.

7) *The Presence or Absence of Working Examples.* There is a lack of examples using the compositions to "prevent" oral diseases from occurring.

8) *The Quantity of Experimentation Needed.* The applicant needs to provide examples of using the compositions on animals that are likely to develop oral diseases. Other experiments include using the compositions on animals who have had plaque, gingivitis, periodontal disease or oral malodor and no longer have them, and show that they do not develop the conditions again. The applicant also needs to provide experiments that show once the compositions are used the conditions no longer occur.

9) *Suggested language.* Since the term "treating" is a broad term, it will inherently cover treatments in which some protective function may also be present. Accordingly, the examiner recommends simply reciting a composition for "treating" plaque, gingivitis, periodontal disease and oral malodor.

Claim Rejections - 35 USC § 102 - Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1) Claims 1 and 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller et al. (US 6,426,362).

Miller discloses compositions comprising tocopherol and a synergist selected from lactoferrin, flavonoids and/or a combination of flavonoids (col. 4, lines 31-40 and col. 26, lines 62-67). Flavanes include flavanones such as epigallocatechin gallate. The compositions may be given to humans, farm animals and pets and may be formulated into pet foods, encompassing claims 5-6. The compositions are used for the purpose of alleviating stresses to metabolic pathways such as reactive oxygen species. The reference anticipates the instant claims insofar as it discloses a composition comprising lactoferrin and epigallocatechin gallate.

2) Claims 1 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Dana (US 2003/0003059).

Dana discloses dentifrice compositions for treating dental related conditions in humans and animals such as pets. The compositions include compounds rich in fluoride including plants or extracts of green tea, which comprises epigallocatechin gallate. Antioxidants including polyphenols may be added to the compositions. Vitamins such as vitamin E and vitamin A (contains carotenoids) may be used in the compositions as additives (paragraph 0048). They may comprise 0.05 to 5% of the compositions. Lactoferrin is included from about 1% to about 3% of the compositions (paragraph 0050). The compositions may be formulated into toothpastes, gels, paste pills, sprays, solutions, lozenges, gums, soaked napkins, dental floss and any other form which may be administered orally. The reference anticipates the instant claims insofar as it discloses a composition comprising lactoferrin and epigallocatechin gallate.

Claim Rejections - 35 USC § 103 - Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 2-4 and 8-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (US 6,426,362) in view of Day et al. (US 2003/0008062).

The primary reference, Miller et al., is discussed above and discloses compositions comprising tocopherol and/or lactoferrin and flavonoids. The reference differs from the instant claims insofar as it does not disclose vitamin C and a carotenoid in the compositions.

Day et al. disclose compositions to treat oral conditions in humans and animals such as pets. The compositions comprise antioxidant such as vitamin E, ascorbic acid, carotenoids, polyphenols and mixtures thereof (paragraph 0083). Polyphenols, which may be extracted from green tea, are also used to treat malodor. The reference differs from the instant claims insofar as it does not disclose lactoferrin being used in the compositions.

It is *prima facie* obviousness to select a known material based on its suitability for its intended use. *See Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See, e.g., In re Linder, 457 F.2d 506, 507 (CCPA 1972); see also In re Dial, 326 F.2d 430, 432 (CCPA 1964). It would have been obvious to one of ordinary skill in the art to have used the antioxidants in the compositions of the primary reference motivated by the desire to use compounds for their imparted effect, as supported by

case law and to use compounds that can treat gum disease and malodor in the oral cavity as taught by the secondary reference.

In regards to the amount of each component recited in the instant claims, normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. In re Aller 105 USPQ 233, 235 (CCPA 1955). It would have been obvious to one of ordinary skill in the art to have adjusted the amounts of each component motivated by the desire to optimize efficacy for the condition being treated, as supported by cited precedent.

2) Claims 2-4 and 8-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (US 6,426,362) in view Shields, Jr. et al. (US 6,156,355).

The primary reference Miller et al. is discussed above and discloses compositions comprising tocopherol and/or lactoferrin and flavonoids. The reference differs from the instant claims insofar as it does not disclose vitamin C and a carotenoid in the compositions.

Shields, Jr. et al. disclose canine food formulations to meet the specific needs of different types of dogs. The compositions comprise vitamin E, beta-carotene and ascorbic acid or some source of vitamin C (col. 5, lines 40-50). The reference differs from the instant claims insofar as it does not disclose the compositions comprise epigallocatechin and lactoferrin.

It is *prima facie* obviousness to select a known material based on its suitability for its intended use. *See Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See, e.g., In re Linder, 457 F.2d 506, 507 (CCPA 1972); see also In re Dial, 326 F.2d 430, 432 (CCPA 1964). It would have been obvious to one of ordinary skill in the art to have used the vitamin E, beta-carotene and ascorbic acid or some source of vitamin C in the pet food formulations motivated by the desire to use components utilized for nutritional value in pet foods. It would have been obvious to one of ordinary skill in the art to have adjusted the amounts of each component motivated by the desire to optimize efficacy for the condition being treated, supported by cited precedent above.

Claims 1-6 and 8-16 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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